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**REMARKS**

These remarks are submitted in response to the Office Action of April 9, 2003. In the Office Action, the Examiner rejected claims 10-13, 16, 17, and 21-24 35 U.S.C. under § 102(e) as being anticipated by U.S. Patent 6,270,475 to Bestetti et al. ("Bestetti"), U.S. Patent 5,954,687 to Baudino et al. ("Baudino"), or U.S. Patent 6,010,494 to Schafer et al. ("Schafer"). The Examiner also rejected claims 10, 12, 13, 15, 16, 27, 40 and 54 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent to Donaldson et al. ("Donaldson"). Finally, the Examiner rejected claims 28-39, 41-53, and 55-62 under 35 U.S.C. § 103(a) as being unpatentable over Schafer in view of Bestetti, Donaldson, and U.S. Patent 5,607,390 to Patsalos et al. ("Patsalos").

In this amendment, Applicants have cancelled claims 41 and 55, amended claims 10, 12-17, 21, 27, 40 and 54, and offered arguments to overcome various rejections of the claims. Applicants respectfully submit that pending claims 10, 12-17, 21-24, 27-39, 40, 42-53, 54, and 56-62 are patentable over the prior art of record. Accordingly, Applicants request a notice of allowance.

**Rejections under 35 U.S.C. § 102****35 U.S.C. § 102(e) Rejection Based On Bestetti, Baudino, or Schafer**

In the Office Action, the Examiner rejected claims 10-13, 16, 17, and 21-24 under 35 U.S.C. § 102(e) as being anticipated by Bestetti, Baudino, or Schafer. A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. MPEP § 2131.

Bestetti discloses a "percutaneous port body" with a single catheter 2 beneath the skin. *Bestetti*, col. 3, l. 66; *FIGS. 1 & 2*. Bestetti discloses that "[a]n infusion hose can be pushed . . . into the inside of the port body," and the catheter 2 then "moves the drug . . . to the desired site inside the body." *Bestetti*, col. 2, ll. 57-62. However, Bestetti does not disclose that the infusion hose, or any other device, enters or travels through the catheter 2.

Baudino discloses an injection port with a "modified burr hole ring adapted to engage the skull at a burr hole drilled therein." *Baudino*, *abstract*. Baudino discloses a single catheter extending into the patient from the injection port. *Baudino*, *FIGS. 1 & 2*. Besides the stylet 14,

which is placed in “the catheter 12 to enhance its rigidity during insertion into the brain 1,” Baudino does not disclose that any other device enters or travels through the catheter 12. *Baudino, col. 3, 28-31.*

Schafer discloses a connection system for connecting a cannula to a device that has a single catheter 42 beneath the skin. *Schafer, abstract, FIGS. 5 & 6.* Because “[t]he diameter of the aperture 3 opposing the cannula 21 is smaller than the spherical end 22 of the cannula,” “the cannula cannot be fully pushed through the chamber 1 but only up to the stop of the spherical cannula end 22.” *Schafer, col. 2, ll. 54-55; col. 3, ll. 1-3; FIG. 1.* Thus, Schafer does not disclose that any device enters or travels through the catheter 42.

Bestetti, Baudino, and Schafer do not disclose a “port body and tube . . . adapted to allow a detection device to be guided through the tube into the interior of the living body,” as recited in independent claim 10. Also, Bestetti, Baudino, and Schafer do not disclose a port member “comprising a feed tube and an aspiration tube extending away from said elastic closing diaphragm and into an interior region of the body,” as recited in independent claim 16.

For at least these reasons, Bestetti, Baudino, and Schafer fail to anticipate each and every element as set forth in independent claims 10 and 16. Also, since pending claims 12-14 and 21-22 depend on independent claim 10, and pending claims 17 and 23-24 depend on independent claim 16, the above arguments apply *a fortiori* to the rejection of these dependent claims. Therefore, Applicants respectfully request that the anticipation rejection based on Bestetti, Baudino, and Schafer be reconsidered and withdrawn.

Support for a “port body and tube being adapted to allow a detection device to be guided through the tube into the interior of the living body” may be found at pages 9-10 of the specification as filed and in FIG. 1. Support for a port member “comprising a feed tube and an aspiration tube extending away from said elastic closing diaphragm and into an interior region of the body” may be found at page 8, lines 12-15 of the specification as filed and in FIG. 1.

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35 U.S.C. § 102(b) Rejection Based On Donaldson

In the Office Action, the Examiner also rejected claims 10, 12, 13, 15, 16, 27, 40 and 54 under 35 U.S.C. § 102(b) as being anticipated by Donaldson. A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. MPEP § 2131.

Donaldson discloses an earplug “composed of a resilient material that permits the earplug to generally conform to the shape of an ear canal that receives the earplug.” *Donaldson, col. 2, ll. 58-60*. The resilient material is “a soft molded foam or Silastic <sup>TM</sup>.” *Donaldson, col. 4, ll. 1-2*. In other words, Donaldson discloses an earplug that is made of resilient material much like a standard foam earplug that is used for hearing protection. Thus, Donaldson does not disclose “a port body with an elastic self closing diaphragm,” “a generally hollow enclosure containing an elastic self-closing diaphragm,” “a port member containing an elastic closing diaphragm,” “an elastic self closing diaphragm located in a port body,” “an elastic self closing diaphragm . . . contained within a port body,” nor “an elastic self closing diaphragm,” as recited in independent claims 10, 15, 16, 27, 40 and 54, respectively.

Donaldson relies on the conforming nature of its foam body to hold it in place within the ear canal. Alternatively, to hold the foam body in place within the ear canal, Donaldson relies on an “optional adhesive” carried by the flange members 24, 26 for adhering the flange members 24, 26 to the ear surface. *Donaldson, col. 4, ll. 31-34; col. 5, ll. 13-19*. Thus, Donaldson does not disclose a “port body implantable in the skin of the living body,” “a port body implanted in the skin of a living body,” “port member implanted in the skin,” “a port body implanted in the skin of a body,” “a port body implanted in the skin of a living body,” nor “an elastic self closing diaphragm implanted in the skin of a living body,” as recited in independent claims 10, 15, 16, 27, 40 and 54, respectively.

For at least these reasons, Donaldson fails to anticipate each and every element as set forth in independent claims 10, 15, 16, 27, 40 and 54. Therefore, Applicants respectfully request that the anticipation rejection based on Donaldson be reconsidered and withdrawn.

Support for “a port body with an elastic self closing diaphragm,” and similar claim elements, may be found at page 8, lines 10-11 of the specification as filed and in FIG. 1. Support

for “a port body implanted in the skin of a living body,” and similar claim elements, may be found at page 8, lines 4-7 of the specification as filed and in FIG. 1.

35 U.S.C. 103(a) Rejection Based On Schafer in view of Bestetti, Donaldson, & Patsalos

In the Office Action, the Examiner rejected claims 28-39, 41-53, and 55-62 under 35 U.S.C. § 103(a) as being unpatentable over Schafer in view of Bestetti, Donaldson, and Patsalos. In order for a combination of references to establish a case of prima facie obviousness, three requirements must be met:

1. there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings;
2. there must be a reasonable expectation of success; and
3. the prior art references when combined must teach or suggest all the claim limitations.

MPEP §2142.

**1. The Combination Is Improper Because It Lacks The Necessary Suggestion Or Motivation To Modify Or Combine The References.**

“The genius of invention is often a combination of known elements which in hindsight seems preordained. To prevent hindsight invalidation of patent claims, the law requires some ‘teaching, suggestion or reason’ to combine cited references. When the art in question is relatively simple, as is the case here, the opportunity to judge by hindsight is particularly tempting. Consequently, the tests of whether to combine references need to be applied rigorously.” McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351 (Fed. Cir. 2001) (cites omitted). For at least two reason, Applicants’ respectfully submit that inappropriate hindsight is the basis for the combination of Schafer in view of Bestetti, Donaldson, and Patsalos. First, Schafer teaches away from its combination with Patsalos. Second, Donaldson is non-analogous to Schafer, Bestetti, and the claimed invention.

**a. The combination is improper because Schafer teaches away from its combination with Patsalos.**

The is no suggestion to combine if a reference teaches away from its combination with another source. Tec Air, Inc. v. Denso Manufacturing Michigan, Inc., 192 F.3d 1353, 1360 (Fed. Cir. 1999). Where a first prior art reference teaches away from a second prior art reference, this alone can defeat an claim of obviousness. Winner International Royalty Corp. v. Wang, 202 F.3d 1340, 1349-50 (Fed. Cir. 2000).

Schafer discloses a connection system for connecting a cannula to a device that has a single catheter 42 beneath the skin. *Schafer, abstract, FIGS. 5 & 6*. Because “[t]he diameter of the aperture 3 opposing the cannula 21 is smaller than the spherical end 22 of the cannula,” “the cannula cannot be fully pushed through the chamber 1 but only up to the stop of the spherical cannula end 22.” *Schafer, col. 2, ll. 54-55; col. 3, ll. 1-3; FIG. 1*. Thus, Schafer teaches away from a tube or analyzing device passing through its self closing diaphragm 4 and into its catheter 42. In other words, Schafer teaches away from passing Patsalos’s dialysis probe through Schafer’s self closing diaphragm 4 and into Schafer’s catheter 42. As a result, Schafer and Patsalos are not properly combinable.

Without the combination of Schafer and Patsalos, the obviousness rejection is unable to account for “analyzing the subject fluids via a first tube disposable within the elastic self closing diaphragm and the introduction element,” as recited in independent claim 40. Since pending claims 42-53 depend on independent claim 40, the above argument applies *a fortiori* to the rejection of these dependent claims. Therefore, Applicants respectfully request that the obviousness rejection be reconsidered and withdrawn.

**b. The combination is improper because Donaldson is nonanalogous art to Schafer, Bestetti, Patsalos And the Applicants’ claimed invention.**

Where a reference, as in the case of Donaldson, is from such a diverse art that a person of ordinary skill in the claimed art would not look to that art to solve the problem treated by the claimed invention, the art is considered nonanalogous, which is the antithesis of prima facie obviousness. Applicants’ invention, as recited in independent claim 27, is a device for subject fluid analysis, the device comprising an elastic self closing diaphragm located in a port body implanted in the skin of a body and a feed element being suitable for delivery of a substance into

a subject. Similarly, Applicants' invention, as recited in independent claim 54, is a method of analyzing subject fluids and providing substances to the subject fluids comprising the steps of accessing a site through an elastic self closing diaphragm implanted in the skin of a living body and delivering a substance to the site via a feed element associated with the elastic self closing diaphragm.

Schafer depicts a device that is implanted in the skin, the device having a single catheter 8 beneath the skin. *Schafer, abstract, FIG. 5*. The catheter 8, 42 provides "a drug channel leading from an infusion hose 23 into the organism." *Schafer, col. 3, ll. 39-40, FIGS. 5 & 6*.

Bestetti depicts a port body that is implanted in the skin, the device having a single catheter 2 beneath the skin. *Bestetti, col. 3, l. 66; FIGS. 1 & 2*. Like Schafer, Bestetti's catheter 2 provides a drug channel leading from an infusion hose into the organism. *Bestetti, col. 2, ll. 57-62*.

Donaldson, on the other hand, depicts an earplug "composed of a resilient material that permits the earplug to generally conform to the shape of an ear canal that receives the earplug." *Donaldson, col. 2, ll. 58-60*. The earplug allows a topical anesthetic or sterilizing fluid to be "introduced into the ear canal and held securely therein for a period of time so that topical anesthetization or sterilization is accomplished. The device seals these fluids securely in place in the ear canal, even if the patient [such as a small child] moves or fidgets." *Donaldson, col. 6, ll. 61-67*. Donaldson relies on the conforming nature of its foam body to hold it in place within the ear canal. Alternatively, to hold the foam body in place within the ear canal, Donaldson relies on an "optional adhesive" carried by the flange members 24, 26 for adhering the flange members 24, 26 to the ear surface. *Donaldson, col. 4, ll. 31-34; col. 5, ll. 13-19*.

Donaldson, unlike Schafer, Bestetti, and the inventions claimed in independent claims 27 and 54, is not directed to a device that is implanted in the skin and has a catheter for delivering fluids into the tissue of a living body. Neither is Donaldson reasonably pertinent to Schafer, Bestetti, or Applicants' inventions as recited in independent claims 27 and 54. Thus, the combination is improper because Donaldson is nonanalogous art to Schafer, Bestetti, and Applicants' claimed invention.

Without being able to properly combine Donaldson with the other references, the obviousness rejection is unable to account for a “device comprising: . . . a feed element associated with the self closing diaphragm, . . . ; and an aspiration element associated with the self closing diaphragm,” as recited in independent claim 27. Also, the obviousness rejection is unable to account for “[a] method of analyzing subject fluids and providing substances to the subject fluids comprising . . . delivering a substance to the site via a feed element . . . ; and analyzing the subject fluids via an aspiration element,” as recited in independent claim 54.

Since pending claims 28-39 depend on independent claim 27, and pending claims 56-62 depend on independent claim 54, the above argument applies *a fortiori* to the rejection of these dependent claims. Therefore, Applicants respectfully request that the obviousness rejection be reconsidered and withdrawn.


### CONCLUSION

In view of the above amendments and preceding remarks, it is respectfully urged that the rejection of the claims be reconsidered and withdrawn and that pending claims 10, 12-17, 21-24, 27-39, 40, 42-53, 54, and 56-62 be allowed. However, should any issue remain unresolved, the Examiner is invited to telephone the undersigned to expedite the allowance.

Respectfully submitted,

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